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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/618,990

07/14/2003

Scott Cunningham

2850

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50855

7590

07/21/2010

Tyco Healthcare Group LP

d/b/a Covidien

555 Long Wharf Drive

Mail Stop 8-N1, Legal Department

New Haven, CT 06511

EXAMINER

RYCKMAN, MELISSA K

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/618,990	Applicant(s) CUNNINGHAM ET AL.	
	Examiner MELISSA RYCKMAN	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 12, 14, 15, 20-22, 24 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 12, 14, 15, 20-22, 24 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to arguments filed 5/17/10. Applicant's arguments, filed 5/17/10, with respect to the sole pair of planar surfaces have been fully considered and are persuasive (the applicant has not previously argued Allen lacking this limitation). The finality of the office action dated 3/15/10 has been withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9,12,14,15,20-22,24 and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The language regarding "each side including one sole pair of planar surface portions" is considered new matter. It is not shown in the application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9,12,14,15,20-22,24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen (U.S. Patent No. 5,403,344) and further in view of Burchette, Jr. (U.S. Patent No. 5,057,082) and Suzuki (U.S. Patent No. 4,565,545).

Claims 1, 12 and 13:

Allen teaches a surgical needle, which comprises:

- an elongated substantially linear needle body (18) defining a central longitudinal y-axis along which the needle body extends and transverse x and z-axes, the needle body including a central shaft portion (12)
- a first suture end portion (16) for attachment to a suture (capable of attaching to a suture) and a second needled end portion (18) for penetrating tissue
- the needled end portion (18) further defining an enlarged transition portion adjacent the central shaft section (portion curved out near number 20 in Fig. 2) with at least an x-dimension "xt" greater (portion near number 24 in Fig. 4) than a corresponding x-dimension "xl" of the central shaft (diameter of 26)
- the z-dimension and x-dimension are offset from each other by 90 degrees and are both transversely perpendicular to the central longitudinal axis
- the needled end portion having three sides (20) which intersect to define three cutting edges and terminate at a needle point (Fig. 3), each side

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including a pair of planar surface portions arranged in oblique relation to define a general concave appearance to each side (Fig. 4).

Allen does not specify each side having one sole pair of planar surfaces, however Burchette teaches a cutting tip with each side having one sole pair of planar surfaces (Fig. 6). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the cross section of Burchette with the device of Allen, as this is appropriate in use for specific procedures and types of tissue.

Allen does not specify some of the geometry as specified in the claims; however Suzuki teaches:

- the needle point (point extending from 1b, Fig. 8) being displaced a predetermined distance with respect to the longitudinal axis (Fig. 8) and wherein the predetermined distance is less than $\frac{1}{2}$ the x-dimension "xt" of the enlarged transition portion (Fig. 8)
- at least one side of the needled end portion being displaced by an angle alpha from a plane parallel to the longitudinal axis (Fig. 8), the angle alpha being between about 2° and 10° (col. 4, ll. 47, alpha is derived using theta using the alternate interior angles theorem) wherein the side of the needled end portion displaced by angle alpha from the plane parallel to the longitudinal axis has a substantially continuous slope between the enlarged transition portion and the needle point

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It would have been obvious to one of ordinary skill in the art to use the geometry of Suzuki with the device of Allen, as the angle blade increases the surface area of the blade and aids in cutting the tissue.

Claim 2:

Allen teaches the planar surface portions of each side are arranged to intersect along a median plane bisecting a respective side to define a substantially symmetrical concave appearance to the respective side (Fig. 3).

Claims 3, 14 and 15:

Allen teaches the enlarged transition portion defines a z-dimension "zt" (24, Fig. 4) greater than or equal to a corresponding z-dimension "zl" of the central shaft portion (Fig. 4).

Claim 4:

Allen teaches the x-dimension "xt" (Fig. 4) and z-dimension "zt" (Fig. 4) correspond to the height and width respectively of the transition portion of the needle end portion.

Claims 5-7:

Allen teaches the planar surface portions of each side intersect to define an included angle ranging from about 160° to about 175° (20,, Fig. 2), the included angle is about 170° (20 Fig. 2), two of the cutting edges intersect at the needle point and define an angle of about 22° to about 25° (Fig. 4).

Claim 8:

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Allen teaches the central shaft portion (12) defines a distal shaft transition portion (portion near number 20, Fig. 3) adjacent the needled end portion, the distal shaft portion defining a cross-section of general triangular character (Fig. 4).

Claim 9:

Allen teach the distal shaft portion includes three planar surfaces interconnected by rounded surfaces (Fig. 4, 26 is rounded).

Claims 20 and 21:

Allen teaches each side of the needle end portion (Fig. 4) includes a single pair of first and second planar surface portions arranged in oblique relation (Fig. 2), the first and second planar portions being the pair of planar portions. Allen teaches each side of the needle end portion includes a single pair of first and second planar surface portions arranged in oblique relation (Fig. 2 and 4), the first and second planar portions being the pair of planar portions.

Claims 22 and 25:

Allen teaches each cutting edge is substantially linear (Fig. 4, 20, substantially linear, Fig. 2).

Claim 24:

Allen teaches the needle body is adapted to assume a curved configuration (Fig. 1).

Response to Arguments

Applicant's arguments filed 5/17/10 regarding Allen lacking teaching each side having a sole planar surface pair have been fully considered but are moot in view of a new rejection. The applicant argues Suzuki does not teach an angle of about 2 to about 10 degrees, however using the alternate interior angle theorem and the information found in col. 4, ll. 47 this can be deduced from the given angle theta.

Conclusion

Applicant's amendment dated 11/24/09 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA RYCKMAN whose telephone number is

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(571)272-9969. The examiner can normally be reached on a flexible schedule, email address is melissa.ryckman@uspto.gov.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571)-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MKR
/Melissa Ryckman/
Examiner, Art Unit 3773

/Darwin P. Erez/
Primary Examiner, Art Unit 3773